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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,385	03/29/2004	Masahiro Okuda	Q80589	3080

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,385	OKUDA ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,8,9 and 15-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,8,9 and 15-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/6/07, 6/18/07*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application

6)☐ Other: _____.

DETAILED ACTION

1. Claims 6, 8, 9 and 15-22 are pending and are under consideration.

2. Applicant's IDS filed 4/6/07 and 6/18/07 have been acknowledged.

However, Applicants have not provided copies of foreign patent documents and non-patent literature documents for the IDS filed on 6/18/07, only U.S. Patent documents have been acknowledged from the IDS filed on 6/18/07.

3. In light of Applicants' cancellation of claims, the following rejections remain.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 6, 8, 9 and 15-22 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 5,834,223, of record, as is evidenced by Galli et al. (Blood, 1999, vol. 93(7): 2149-2157), of record, in view of U.S. Pat. No. 4,914,040, of record, for the reasons set forth in the office action mailed 11/6/06.

Applicants' arguments filed on 4/6/07 have been fully considered but they were not persuasive.

Applicants traversed the rejection based on that the '223 patent does not teach or suggest a coagulation time reagent containing a first composition for coagulation and an anti-phospholipid antibody capturing component that is selected from the group consisting of antibodies, plasma, serum, and immunoglobulin, where the anti-phospholipid capturing component is derived from vertebrate animals other than humans. Therefore, the combination of teachings is not obvious.

Contrary to Applicants' arguments, the '223 patent teaches a reagent for measuring coagulation time comprising a composition for coagulation such as procoagulant (col. 3-4 overlapping paragraph, claims 1, 9-10, in particular), the procoagulant comprises calcium ions, phospholipids and ellagic acid as an activator (col. 4, line 54, in particular) and the human plasma or blood samples are used (Examples 1-9, in particular). The referenced reagent for measuring coagulation time is comparable to the claimed first composition without the non human derived anti-phospholipid antibody capturing component.
The '223 patent further teaches various phospholipid/calcium based procoagulant test system for measuring clotting time such as RVVT using viper venom, KCT using kaolin or CSCT using silica (col. 4, lines 38-61, in particular).

Moreover, the '223 patent teaches the reagent for measuring coagulant time can be packaged in a kit in separate containers (col. 6, lines 39-53) and the reagent samples can be prepared differently in the presence or absence of the test constituents/controls and with the different concentrations (col. 5, lines 18-45, in particular).

As is evidenced by Galli et al., the phospholid/calcium based assays such as RVVT, KCT and CSCT detect phospholipid antibody and further indicate presence of human lupus anticoagulant (p. 2152-2153, Tables 4-5, in particular).

Claims 15-17, 21 and 22 are included in this rejection because the '223 patent teaches packaging calcium ions separately in a kit (col. 6, lines 39-50, in particular) and calcium is being added lastly before measuring the clotting time (claim 1, in particular).

Claim 9 is included in this rejection because packaging the preparatory reagents based on the presence or absence of "antibodies, plasma, serum and immunoglobulin derived from vertebrate animals other than human", (non-human antibody, thereafter) and further packaging based on the presence or absence of the calcium ions are well within the purview of the optimization of the ordinary skill in the art.

The '223 patent does not teach use of non-human antibody in a reagent for measuring coagulation time and the deficiency is cured by the '040 patent.

As discussed in the office action mailed 11/6/06, the '040 patent teaches that any assays involving in human blood samples have interfering factors. The interfering factors compete with analytes in the test samples and interfere with specificity and sensitivity (false negative or false positive) of the assays (col. 1, lines 6-45, in particular).

The '040 patent further teaches that the addition of antibody from the different source from the test material (e.g. a test material of human blood would require antibody from non-human source) avoid the competition of the interfering factors (col. 3-4, col. 4, lines 30-34, in particular) as a rule.
Thus, the elimination of the competition between interfering factors and the analyte of test samples improves the assay system (col. 2, lines 60-65, in particular).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to add non-human antibody (antibody from the different source from the test material) as taught by the '040 patent in the reagent for measuring coagulation time as taught by the '223 patent.

One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because addition of the secondary antibody from the different source from the test material eliminates competition between the interfering factors from the human blood and the analyte of the assay system and improves the assay system as taught by the '040 patent.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

As one cannot show nonobviousness by attacking references individually where the rejections are based on the combinations of references. See MPEP 2145(d). Therefore, the combination of teachings remains obvious.

6. The following new rejections are necessitated by Applicant's amendments to the claims filed on 4/6/07.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6, 8, 9 and 15-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The specification as filed does not provide a written description "anti-phospholipid antibody capturing component". Applicant has indicated that the support can be found in p. 9-10 overlapping paragraph. However, the paragraph is associated with "at least one component selected from the group consisting of the antibodies, the plasmas, the serum and the immunoglobulins derived from the vertebrate animals other than humans is contained in the inventive reagent". There is no support in the specification that the inventive reagent used in the reagent kit for detecting anti-phopholipid antibody is an anti-phospholipid capturing component.

9. No claims are allowable.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
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July 5, 2007

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